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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,572	06/18/2001	Reto Naef	4-30754A	2901

1095 7590 10/03/2003

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,572

Applicant(s)

NAEF, RETO

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 21, 26-27 and 29-31 under 35 U.S.C. 103(a) as being unpatentable over WO 9428902 in view of Sui et al (6,077,841) is maintained.

The rejection of claims 25, 28 and 32-33 under 35 U.S.C. 103(a) as being unpatentable over WO 9428902 in view of Sui et al (6,077,841) as applied to claims 21, 26-27 and 29-31 above, and further in view of Purewal et al (5,225,183) is maintained.

Response to Arguments

Applicant's arguments filed 07/16/03 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that WO 9428902 teaches the use of a series of pyrazolo[4,3-d]pyrimidine-7-ones inhibitors of cGMP PDEs for the treatment of impotence, for oral and parenteral administration, but does not suggest administration via inhalation. Applicant also states an argument that Sui et al describes an alternative class of PDE

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V inhibitors, and while teaching various routes of administration including inhalation, Sui does not suggest that sildenafil or its analogues can be administered in inhalation form.

However, this is not persuasive because WO 9428902 is clearly teaching the specific compounds of the claims and is teaching their use to treat sexual dysfunction. WO teaches their use in an oral or parenteral form. Sui et al is clearly teaching that sildenafil is used in tablet form for treating sexual dysfunction and is stating some disadvantages of this form of the drug and suggest other forms of the drug and other routes of administration. Sui is clearly teaching that the class of PDE V inhibitors would be expected to increase the concentration of cGMP (col. 2, lines 49-51) and that the inhibitors can be administered in forms including inhalation, metered aerosol, intranasal etc (col. 9, lines 55-65). It would be obvious to one of ordinary skill in the art to combine the two references and conclude that any compound of the class PDE V inhibitors can be made in an inhalation form because of its convenience of use and fast onset of action as well as reduced side effect profile.

Applicant is arguing that Sui acknowledges that mechanical devices are not favored and tend to be used only as a last resort, and therefore an oral form of the medication is preferred. This is not correct. The statement of col. 2, lines 14-16 of Sui's reference is comparing a device for introducing the medication directly in patient's penis to oral form. This is not to mean that device includes an inhalation device, which is easy to use and quite discrete.

Applicant argues that Purewal, while teaching aerosol formulations utilizing particular propellants and various types of medicaments, does not teach or suggest any of the specific compounds recited in the amended claim 21. This is not persuasive because again, applicant is attacking references individually. One of ordinary skill would be motivated to look for a suitable propellant when working on preparing an aerosol formulation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

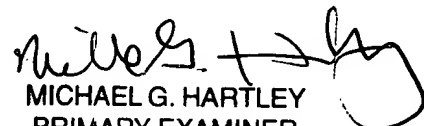
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghghatian
September 23, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER